DOCKET NO.: C1039.70073US00

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Arthur M. Krieg et al.

Serial No.: 10/743,625 Confirmation No.: 9416

Filed: December 22, 2005

For: IMMUNOSTIMULATORY NUCLEIC ACID

Examiner: Nita M. Minnifield

Art Unit: 1645

#### CERTIFICATE OF ELECTRONIC FILING UNDER 37 C.F.R. § 1.8

The undersigned hereby certifies that this paper, along with any paper referred to as being attached or enclosed, is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4), on the 3rd day of December, 2010.

Electronic Signature for Sharon R. Lloyd: /Sharon R. Lloyd/

#### MAIL STOP RCE

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

# STATEMENT FILED PURSUANT TO THE DUTY OF DISCLOSURE UNDER 37 C.F.R. §§ 1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§ 1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

#### PART I: Compliance with 37 C.F.R. § 1.97

This Information Disclosure Statement has been filed before the mailing of a first Office Action after the filing of a Request for Continued Examination under 37 C.F.R. § 1.114.

No fee or certification is required.

#### PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified PTO/SB/08). The order of presentation of the references should not be construed as an indication of the importance of the references.

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The Applicant hereby makes the following additional information of record in the above-identified application.

The Applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

Serial No.	<u>Filing Date</u>	<u>Inventor(s)</u>	Docket No.
12/600,368	11-16-2009	Uhlmann et al.	*C1041.70054US01
12/681,800	04-06-2010	Uhlmann et al.	*C1041.70055US01
12/835,000	07-13-2010	Hartmann et al.	*C1039.70044US03
12/881,475	09-14-2010	Krieg et al.	*C1037.70059US03
12/946,227	11-15-2010	Krieg	*C1039.70077US02
12/946,379	11-15-2010	Uhlmann et al.	*C1041.70045US02
12/946,806	11-15-2010	Ahluwalia et al.	*C1037.70035US03

<sup>\*</sup>A copy of this reference is not provided as the Office has waived the requirement under 37 C.F.R. 1.98(a)(2)(iii) for submitting a copy of a cited U.S. patent application if it is scanned to the Image File Wrapper system and is available on Private PAIR.

The Applicant would like to bring to the Examiner's attention the following other information:

Interview Summary mailed 11/05/2010 for Application No. 09/337,584 (C1039.70020US00) Notice of Allowance mailed 09/09/2010 for Application No. 09/337,584 (C1039.70020US00)

# PART III: Explanation of Non-English Language References and Remarks Concerning Other Information Cited

Applicants of the instant patent application are also named inventors on an issued patent US patent No. 6,207,646 B1, which was involved in an Interference (Interference No. 105,171). The instant patent application derives priority from US 6,207,646 B1. In view of the priority, Applicants have included on previous Information Disclosure Statements a listing of all of the motions filed, the judgment rendered by the Board of Patent Appeals and Interferences, appeal briefs, and appeal decision, which considered the 35 U.S.C. §135(b)(1) motion dispositive.

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Copies of these documents were cited in previously filed Information Disclosure Statements for this application. If the Examiner would like any additional information on this subject, she is encouraged to contact Applicant's representative at the number listed below.

Additionally, the instant patent application is related to US Serial No. 09/337,584 which was in Interference No. 105,526. Copies of the Interference documents were cited in previously filed Information Disclosure Statements for this application. A Terminal Disclaimer over US 09/337584 is filed herewith. In an IDS filed on July 17, 2009 in US09/337,584, Applicant informed the Office of a Board Order dated January 16, 2009 (Paper No. 19) from Interference No. 105,674. In that Order, the Board required that Applicant request the Examiner to determine whether an obviousness-type double patenting rejection should be made in US09/337,584 over US Patent 7402572. Applicant brings this Order to the attention of the Examiner in the instant patent application, because the instant patent application was filed to copy the claims of an issued US patent that was the subject of the Interference No. 105,674. Thus, the Office may also consider the issue of double patenting over US Patent 7402572 in the instant patent application.

On pages 9-10 of the same Order, the Board considered and denied a motion by Party Raz for additional discovery relating to experimental data underlying statements made by Krieg's inventors that appear in several publications. In particular, the Examiner is directed to the discussion of the Kline 1996 and 1997 abstracts and the Kline 1998 article that appears in Raz Motion 1, Krieg Opposition 1, Raz Reply 1, Raz Motion 2, Krieg Opposition 2, Raz Reply 2, Raz Motion 3, Krieg Opposition 3, and Raz Reply 3. Out of an abundance of caution, Applicant submitted documents in US 09/337,584 that may have been produced had Raz's motion been granted. These documents provide the reported details and results of four experiments in which CpG oligonucleotide alone was administered. These documents may be related to the Kline 1996 and 1997 abstracts and the Kline 1998 article. Two of these experiments are dated prior to the September 1996 date of the Kline 1996 abstract. Each of these experiments contained one control group of mice that received CpG oligonucleotide without sensitization, and in each experiment the CpG oligonucleotide reportedly had no effect on eosinophil levels. The remaining two experiments were dated October and December 1996. In these latter experiments, groups of mice were administered egg alone, egg and CpG

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oligonucleotide, egg followed by CpG oligonucleotide, or egg followed by control oligonucleotide. All mice then received SEA. The results, including the effects on eosinophil levels, are shown in the documents submitted herewith.

Furthermore, US patent application 09/337,584 with claims directed to the treatment of asthma was involved in a second Interference (No. 105,674). The Interference ended when Junior party Raz abandoned the contest. The Board entered judgment against Raz for Count 1. Copies of papers filed with respect to that Interference were cited in previously filed Information Disclosure Statements for this application. If the Examiner would like any additional information on this subject, she is encouraged to contact Applicant's representative at the number listed below.

## PART IV: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

- 1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
- 2. The enclosed form PTO-1449 (modified PTO/SB/08) be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
- 3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

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By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. § 102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his or her own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

The Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825 under Docket No. C1039.70073US00 from which the undersigned is authorized to draw.

Respectfully submitted,

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Date: December 3, 2010

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